



HEALTH HOLDING

HAFER ALBATIN HEALTH
CLUSTER
MATERNITY AND
CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank		
Document:	Departmental Policy and Procedure		
Title:	Blood Products Label Validation		
Applies To:	All Laboratory and Blood Bank Staff		
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1. PURPOSE:

- 1.1 The purpose of this policy is to provide guidance to Blood Bank staff to validate blood pack label before accepting for use to ensure safe, accurate and unchangeable unit data while transporting, further processing or storage.

2. DEFINITONS:

- 2.1 Label - an inscription affixed to a unit of blood, component, tissue, derivative, or sample for identification.
- 2.2 Physical property - any property that is measurable, whose value describes a state of a physical system. The changes in the physical properties of a system can be used to describe its changes between momentary states. Physical properties are often referred to as observables
- 2.3 Solvent resistance - the resistance of a label to the action of specific organic liquids.
- 2.4 Environmental Properties Testing - is the measurement of the performance of equipment under specified environmental conditions, such as: extremely high and low temperatures large, swift variations in temperature blown and settling sand and dust salt spray and salt fog very high or low humidity
- 2.5 Blood Pack - A container of blood or one of its components in a suitable volume of anticoagulant obtained from a collection of blood from one donor

3. POLICY:

- 3.1 It is the policy of Blood Bank to ensure blood pack label quality before its use at first time and every new model.
- 3.2 The label shall be firmly attached to the container of all blood and component units.
- 3.3 The label and added portions of the label must have good resistance against tearing, abrasion, peeling and must have accepted adhesiveness strength.
- 3.4 The label and added portions of the label must resist modification or removal label data by alcohol and water
- 3.5 The label and added portions of the label must sustain temperature changes
- 3.6 The label shall correspond to ISBT 128 requirements

4. PROCEDURE:

- 4.1 Check the physical properties of the label against tear, abrasion, peeling and adhesiveness by trying to pull label smoothly by your hand, do it through 10 consequence days and register the result
- 4.2 Check the solvent resistance against water and alcohol by putting little amount of them on part of label and register the result physical properties of the label against tear, abrasion, peeling and adhesiveness through 10 consequence days.
- 4.3 Check the resistance of label against temperature changes by putting label on pack and put some of these bags in fridge and freezer, try to thaw some of frozen pack and check the results, do these 10 consequence days and resister the results.

APPENDIX 7.1

VALIDATION OF LABEL USED FOR BLOOD BAG

DAY	Physical Properties Testing		Solvent Resistance Properties		Environmental Properties Testing	
	PHYSICAL TEST COMPONENTS	RESULTS	TEST COMPONENTS	RESULTS	TEST COMPONENTS	RESULTS
1	1- Tear Resistance		Alcohol Resistance		Cold Temperature	
	2- Abrasion Resistance				Deep Freezer Temperature	
	3- Peel Test		Water Resistance		Hot Temperature (Thawing)	
	4- Adhesiveness					
2	1- Tear Resistance		Alcohol Resistance		Cold Temperature	
	2- Abrasion Resistance				Deep Freezer Temperature	
	3- Peel Test		Water Resistance		Hot Temperature (Thawing)	
	4- Adhesiveness					
3	1- Tear Resistance		Alcohol Resistance		Cold Temperature	
	2- Abrasion Resistance				Deep Freezer Temperature	
	3- Peel Test		Water Resistance		Hot Temperature (Thawing)	
	4- Adhesiveness					
4	1- Tear Resistance		Alcohol Resistance		Cold Temperature	
	2- Abrasion Resistance				Deep Freezer Temperature	
	3- Peel Test		Water Resistance		Hot Temperature (Thawing)	
	4- Adhesiveness					
5	1- Tear Resistance		Alcohol Resistance		Cold Temperature	
	2- Abrasion Resistance				Deep Freezer Temperature	
	3- Peel Test		Water Resistance		Hot Temperature (Thawing)	
	4- Adhesiveness					
	1- Tear Resistance		Alcohol Resistance		Cold Temperature	

6	2- Abrasion Resistance				Deep Freezer Temperature	
	3- Peel Test		Water Resistance		Hot Temperature (Thawing)	
	4- Adhesiveness					
7	1- Tear Resistance		Alcohol Resistance		Cold Temperature	
	2- Abrasion Resistance				Deep Freezer Temperature	
	3- Peel Test		Water Resistance		Hot Temperature (Thawing)	
	4- Adhesiveness					
8	1- Tear Resistance		Alcohol Resistance		Cold Temperature	
	2- Abrasion Resistance				Deep Freezer Temperature	
	3- Peel Test		Water Resistance		Hot Temperature (Thawing)	
	4- Adhesiveness					
9	1- Tear Resistance		Alcohol Resistance		Cold Temperature	
	2- Abrasion Resistance				Deep Freezer Temperature	
	3- Peel Test		Water Resistance		Hot Temperature (Thawing)	
	4- Adhesiveness					
10	1- Tear Resistance		Alcohol Resistance		Cold Temperature	
	2- Abrasion Resistance				Deep Freezer Temperature	
	3- Peel Test		Water Resistance		Hot Temperature (Thawing)	
	4- Adhesiveness					

4.4 Follow the following table and fill it with test results. (See appendix 7.1)
 5.5 Accept only label which pass all tests through the 10 days tests.

5. MATERIALS AND EQUIPMENT:

5.1 **Printer to print labels**
 5.2 Blood Units
 5.3 Alcohol
 5.4 Water
 5.5 Thermometer

6. RESPONSIBILITIES:

6.1 It is responsibility of blood bank technician/technologist assigned in quality assurance section of component section to check label validity before use.

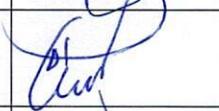
7. APPENDICES:

7.1 Validation of label used for blood bag

8. REFERENCES:

8.1 Guidelines for Good Clinical Laboratory Practices, ICMR, New Delhi, 2008.
 8.2 Quality management system: qualifying, selecting, and evaluating a Referral laboratory; approved guideline -2ed.
 8.3 Good Manufacturing Practice for Blood Establishments, Version 2.0, May 2019, Saudi FDA.

9. APPROVALS:

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